

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF PENNSYLVANIA

EDWARD A. DREISBACH,

Plaintiff,

v.

APP PHARMACEUTICALS, LLC,  
BAXTER HEALTHCARE  
CORPORATION, HOSPIRA INC.,  
and JOHN DOES, 1 THROUGH 75  
(fictitious)

Defendants.

Civil Action No. 3:10-CV-00419

(Judge Kosik)

**FILED  
SCRANTON**

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DEPUTY CLERK

**MEMORANDUM**

Before this court are remaining Defendants' motions for summary judgment. For the reasons which follow, the Defendants' motions for summary judgment are granted in part and denied in part.

**I. BACKGROUND**

Plaintiff filed a Complaint (Doc. 1), followed by an Amended Complaint (Doc. 34). The case started out as a strict liability action based on several named causes, including the Defendants' failure to warn of specific risks of serious side-effects associated with heparin, including heparin induced thrombocytopenia ("HIT") and heparin-induced thrombocytopenia with thrombus ("HITT"). Defendants, Baxter Healthcare Corporations ("Baxter") and APP Pharmaceuticals, LLC. ("APP"), filed motions for summary judgment on January 11, 2013. (Docs. 97, 100.) Defendants

also filed joint motions to exclude the opinions and testimony of Stephen B. Shohet, M.D. and John L. Francis, Ph.D. (Docs. 98, 99.) These joint motions were denied in our Memorandum and Order dated July 22, 2013. (Doc. 134.) The parties fully briefed the motions for summary judgment, and the Court heard oral arguments on September 17, 2013. Therefore, the motions for summary judgment are ripe for disposition.

## II. STANDARD OF REVIEW

Summary judgment is appropriate when “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(c). An issue is “genuine” if there is sufficient evidence with which a reasonable jury could find for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Childers v. Joseph, 842 F.2d 689, 693-94 (3d Cir. 1988) (citing Anderson, 477 U.S. at 248). A factual dispute is “material” if it might affect the outcome of the case. Id. In determining whether an issue of material fact exists, the court must consider the evidence in the light most favorable to the non-moving party. Skerski v. Time Warner Cable Co., 257 F.3d 273, 278 (3d Cir. 2001); White v. Westinghouse Elec. Co., 862 F.2d 56, 59 (3d Cir. 1988). In doing so, the court must accept the non-movant’s allegations as true and resolve any conflicts in his favor. Id. (quoting Gans v. Mundy, 762 F.2d 338, 340 (3d Cir. 1985), cert. denied, 474 U.S. 1010 (1985)); Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976), cert. denied, 429 U.S. 1038 (1977).

A party seeking summary judgment always bears the initial burden of informing

the court of the basis of its motion and identifying those portions of the record that it believes demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). When the non-moving party bears the burden of proof on a particular issue at trial, the movant's initial burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." Id. at 325. After the moving party has met its initial burden, "the adverse party's response . . . must set forth specific facts showing that there is a genuine issue for trial." FED.R.CIV.P. 56(e). It then follows that summary judgment is appropriate if the nonmoving party fails to rebut by making a factual showing "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

### III. DISCUSSION

Defendants' motions for summary judgment are based principally on three alternative grounds: (1) the heparin warnings were adequate; (2) there is no proof that a failure to warn proximately caused Plaintiff's injury; and (3) there is no qualified opinion on medical causation. In the alternative, Defendants seek partial summary judgment on Plaintiff's non-negligence and punitive damages claims.

Under Pennsylvania law, where the adequacy of the warning accompanying a prescription drug is at issue, negligence is the only basis of liability. Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996). Additionally, Pennsylvania applies the learned intermediary doctrine, which holds a manufacturer liable only where it "fails to exercise reasonable care to inform a physician of the facts which make the drug likely to be

dangerous.” Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. 2010) (citing Taurino v. Ellen, 579 A.2d 925, 927 (Pa. Super. 1990)). The manufacturer must warn the physician and not the patient “because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking.” Id. (quoting Taurino, 579 A.2d at 927). “It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.” Id.

The plaintiff, in a failure to warn case, must show “that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff’s injuries.” Salvio v. Amgen, Inc., 810 F. Supp. 2d 745, 752 (W.D. Pa. 2011) (citing Parkinson v. Guidant Corp., 35 F.Supp. 2d 741, 749 (W.D. Pa. 2004)). “A proximate, or legal cause, is defined as a substantial contributing factor in bringing about the harm in question.” Cochran, 3 A.3d 673 at 676. The plaintiff must establish proximate cause by showing that “had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.” Id. (quoting Demmler v. SmithKline Beecham Corp., 671 A.2d 1151 (Pa. Super. 1996)). “To create a jury question, the evidence introduced must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug.” Id. Additionally, the injury suffered must be the “precise injury that the manufacturer allegedly failed to disclose.” Id. at 681.

The Court first disposes of Plaintiff’s non-negligence claims since Pennsylvania

only recognizes negligence as the basis of liability in failure to warn cases involving prescription drugs. Plaintiff, in his memorandum of law in opposition to Defendants' motions for summary judgment (Doc. 113), does not oppose the grant of summary judgment as to his non-negligence claims. Therefore, Plaintiff's non-negligence claims based on strict liability, breach of warranty, and fraud are dismissed as a matter of law, and summary judgment is granted as to these claims.

Defendants' principal argument is that the heparin warnings were adequate. Under Pennsylvania law, adequacy is initially a question of law, but where fact questions exist, the "question of adequacy is one for the jury." In re Avandia Marketing, Sales Practices and Products Liability Litigation, 817 F.Supp. 2d 535, 545-46 (E.D. Pa. 2011) (citing Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1366 (3d Cir. 1992); Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971)). Furthermore, "[f]acially accurate statements of fact regarding a particular risk are not adequate as a matter of law where there are disputes over whether the warning was sufficiently explicit and detailed." Id. at 547-48. The Court previously stated in its Memorandum to Counsel dated July 22, 2013 (Doc. 135), that refusing to exclude Plaintiff's expert testimony resolved Defendants' first ground for summary judgment, because Plaintiff's expert raised a genuine issue of material fact as to the adequacy of the warning. Therefore, summary judgment is denied as to this ground.

Defendants' second ground for summary judgment is that Plaintiff failed to establish proximate causation between the allegedly inadequate warning and Plaintiff's injury. Defendants argue that Plaintiff cannot prove that the alleged inadequate warning was a substantial factor in bringing about the harm, because Plaintiff's

physicians did not read the heparin label, were aware of risks of HITT, and stand by their decisions to prescribe heparin. Defendants argue that the plaintiff has no evidence to establish that there is a reasonable likelihood that a different warning would have prevented the plaintiff from receiving heparin. Plaintiff puts forth deposition testimony from Michael D. Harostock, M.D., Plaintiff's treating physician, and argues that Dr. Harostock would not have given Plaintiff heparin on February 18, 2008, if Defendants issued a dear-healthcare provider letter warning that the duration of heparin should be limited, whenever possible, to less than five days. (Doc. 113, Ex. 26, Harostock Dep.)

The Court recognizes that Dr. Harostock has the duty to use his independent medical judgment in deciding what form of anticoagulant to use on a specific patient, such as the plaintiff. "[T]he information supplied by the drug manufacturer is only one source a physician must consult and he is expected to make an independent medical judgment in determining whether a given drug is appropriate for a particular patient." Lineberger v. Wyeth, 894 A.2d 141, 150 (Pa. Super. 2006). Neither party asked Dr. Harostock if he, utilizing his independent medical judgment, would have given Plaintiff heparin on February 18, 2008, had he received Plaintiff's proposed warnings. Instead, Dr. Harostock was asked whether he would be able to follow a dear-healthcare provider letter, stating that "the duration of heparin should be limited, whenever possible, to less than five days." Viewing the facts in the light most favorable to the non-moving party, the Court finds there is a dispute of material fact since it is unclear from the deposition testimony whether or not Dr. Harostock was testifying to the fact that he would have been able to follow an instruction to use heparin for less than five days specifically in

the plaintiff's case, when utilizing his independent medical judgment. Therefore, since there is a dispute of material fact, the Court denies Defendants' motions for summary judgment on this ground.

The Defendants' third ground for summary judgment is that there is no qualified opinion on medical causation. The Court finds that since Defendants' motion to exclude Dr. Shohet's testimony was denied, there are disputes of material fact as to medical causation presented by Dr. Shohet's expert testimony. Therefore, summary judgment is denied as to this ground.

Lastly, Defendants argue, in the alternative, that partial summary judgment should be granted as to Plaintiff's punitive damages claim. The Court will reserve this issue for trial.

#### **IV. Conclusion**

For the reasons set forth above, Defendants' motion for summary judgment is granted in part and denied in part. An appropriate order is attached.